



**MEMORANDUM**

**From:** Kimberly Benton, Ph.D., Deputy Director, Division of Cellular & Gene Therapies  
Raj Puri, M.D., Ph.D., Director, Division of Cellular & Gene Therapies, OCTGT, CBER

**Date:** October 16, 2015

**BLA/ STN#:** 125518

**Applicant Name:** Amgen

**Date of Submission:** July 28, 2014, major amendment November 28, 2014

**Action Goal Date:** October 27, 2015

**Proprietary Name/ Established Name:** Imlygic

**Proper (Non-Proprietary name):** talimogene laherparepvec

**Indication:** For the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery

**Product Reviewers:** Ramjay Vatsan, Ph.D. (chair)  
Robert Aksamit, Ph.D.  
Andrew Byrnes, Ph.D.  
Michael Havert, Ph.D.

**Branch Chief:** Denise Gavin, Ph.D.

**Material Reviewed/Consulted:**

CMC Review of Original Submission dated October 15, 2015

I agree with the recommendation for approval as stated in the CMC review memo dated October 15, 2015, and have no additional comments.

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Kimberly Benton, Ph.D.

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Raj K. Puri, M.D., Ph.D.